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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,532	10/27/2003	Daniel M. Lafontaine	10527-430002 / 00-0145-CO	1903
26191	7590	06/03/2005	EXAMINER	
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	
DATE MAILED: 06/03/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/694,532	<b>Applicant(s)</b> LAFONTAINE, DANIEL M.	
	<b>Examiner</b> Michael Peffley	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/12/04</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Objections***

Claim 8 is objected to because of the following informalities: the backslash "/" at the end of the claim should be replaced with a period. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is unclear in that it recites "wherein the pull cord includes a pull cord". The language is confusing.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, 8-11 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine (5,868,735) in view of the teaching of Ressemann et al (5,921,958).

Lafontaine discloses a cryoplasty apparatus which includes a catheter (28) with a cooling member (14) at the distal end of the catheter. The cooling member includes a

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balloon, and a thermo-resistive sensor (22) is used to monitor temperature of the balloon. The cooling member includes a heat exchange surface (48) which sprays coolant into the balloon. The catheter also includes an insulating sheath (260) which defines a vacuum lumen. The only feature not taught by Lafontaine is a pull cord attached to the cooling member.

Ressemann et al disclose a similar angioplasty apparatus which includes a catheter with a balloon at the distal end of the catheter for treating angioplasty. Ressemann et al further provide a sheath member (80), and a pull cord (78) which extends through the sheath and is coupled to the cooling member. The pull cord is a guidewire. A ring member (76) attaches the pull cord to the balloon assembly and allows for steering the device.

To have provided the Lafontaine cryoplasty device with a pull cord coupled to the cooling member to facilitate placement of the cooling member in tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Ressemann et al.

Claims 3, 4 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine ('735) and Ressemann et al ('958) as applied to the claims above, and further in view of the teachings of Milder ('215) and Stern et al ('470).

The combination of the Lafontaine and Ressemann et al teachings has been addressed previously. Neither reference discloses the use of an electrode on the balloon structure.

Milder teaches that it is generally known to associate sensing/treatment electrodes in a cryosurgical device. In particular, Milder provide a cryosurgical catheter for the treatment of myocardial tissue, and further provide electrodes to determine electrical activity of tissue subsequent to treating with cryogenic energy. The Milder device does not include a balloon.

Stern et al teach of providing sensing/treatment electrodes on a balloon structure which is filled with a fluid. The electrodes may be provided in a variety of manners, including a printed electrode pad (Figures 6-8). The electrodes are used to sense/treat tissue.

In as much as Milder teaches that it is known to provide a cryogenic catheter device with electrodes to sense tissue conditions resultant from cryogenic treatment, it would have been obvious to one of ordinary skill in the art to have provided the Lafontaine balloon with a conductive pad electrode, as fairly taught by Stern et al, to allow for the sensing and treatment of tissue during the cryogenic procedure.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,666,858. Although the conflicting claims are not identical, they are not patentably distinct from each other because there are only very minor differences in the instant application claims and the patented claims.

### ***Conclusion***

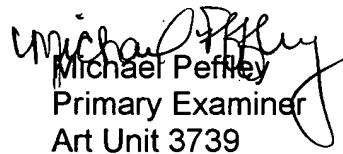
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Toti et al (6,321,749) disclose a balloon catheter with a steering wire (36) attached to the balloon section. Tu et al (6,123,718) and Pomeranz et al (5,800,482) also disclose balloon catheters with a distally attached pull cord/guide wire. Joye et al (5,971,979) disclose a balloon catheter for performing cryoplasty.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael Peffley  
Primary Examiner  
Art Unit 3739

mp  
May 27, 2005